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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/813,483	03/29/2004	Jun Liu	P2026R1	5594

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EXAMINER	
KIM, YUNSOO	
ART UNIT	**PAPER NUMBER**
1644	

DATE MAILED: 12/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/813,483	LIU ET AL.	
	Examiner	Art Unit	
	Yunsoo Kim	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-50* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-50* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Detailed Action

Amendments

1. Claims 1-50 are pending.

It is noted that claims 10-15, 44, and 45 are identical as claims 2-8, 46 and 47 respectively, as recited, directing to the correct independent claim is required.

It is also noted that claims 16-19 are improper dependent claims as they lack proper antecedent bases, anti-IgE antibody, a correction is required.

2. For the examination purposes the following is noted.

The claim 1 and the dependent claims thereof include a recitation of "protein" or "antibody" in the stable liquid formulation of low turbidity. The protein and the antibody do not share substantial structural features as well as physicochemical properties essential to a common utility. Therefore, the restriction has been set forth for each composition and each method employing each recited product as a separate group, irrespective of the format of the claims.

If an additional structurally distinct composition is introduced during the course of prosecution, that do not share a substantial structure feature essential to a common utility, then a supplement restriction requirement may be issued.

Sequence Compliance

3. The instant application is in sequence compliance for patent applications containing amino acid sequence disclosures.

Restriction

4. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-27 drawn to a stable liquid formulation comprising a **protein**, classified in Class 514, subclass 8.

II. Claims 1-27 drawn to a stable liquid formulation comprising an **antibody**, classified in Class 424, subclass 130.1.

III. Claims 28-50 drawn to a method of treating an IgE-mediated disorder using a stable liquid formulation comprising a **protein**, classified in Class 514, subclass 8.

IV. Claims 28-50 drawn to a method of treating an IgE-mediated disorder using a stable liquid formulation comprising an **antibody**, classified in Class 424, subclass 130.

5. Groups I and II are different products. Protein and antibody differ with respect to their structures and physicochemical properties, which require non-coextensive searches; therefore each product is patentably distinct. The protein and the antibody do not share substantial structural physicochemical properties essential to a common utility. Therefore, they are patentably distinct.

6. Groups I/II and III/ IV are related as product and process of using. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)).

Method of treating IgE-mediated disorders can be accomplished by products that differ in physicochemical structures than that set forth in Group I/II. The product claimed in Group I/II can be used in materially different processes, such as *in vitro* assays.

7. Groups III and IV are different methods. These inventions are different with respect to ingredients, method steps, and endpoints, which require non-coextensive searches; therefore, each method is patentably distinct.

8. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art shown by their different classification and recognized divergent subject matter. Further, even though in some cases the classification is shared, a different field of search would be required based upon the structurally distinct products recited and the method of use. Moreover, a prior art search also requires a literature search. It is undue burden for an examiner to search more than one invention. Therefore, restriction for examination purposes as indicated is proper.

Species Election

9. This application contains claims directed to the following patentably distinct species of the claimed inventions wherein:

If Group II or IV is elected: Applicant is required to elect a particular anti-IgE antibody type from the following (e.g. see claims 16-19):

a. rhuMAbE25,
b. rhuMAbE26, or
c. Hu-901.

These species are distinct because of their physicochemical properties, specificity, utility and modes of action. Therefore, they are patentably distinct.

Applicant is required under 35 USC 121 (1) to elect a single disclosed species to which the claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

10. This application contains claims directed to the following patentably distinct species of the claimed inventions wherein:

If Group III or IV is elected: Applicant is required to elect a particular class of IgE-mediated disorder type from the following (e.g. see Claims 28-34, p 58-62 Specification, Method of treatment):

a. allergic rhinitis,
b. allergic asthma,
c. non-allergic asthma,
d. atopic dermatitis,
e. gastroenteropathy,
f. hypersensitivity,
g. allergic bronchopulmonary aspergillosis,
h. parasitic disease,
i. intestinal cystitis,
j. hyper-IgE syndrome,
k. ataxia-telangiectasia,
l. Wiskott-Akdrich syndrome,
m. thymic alymphoplasia,
n. IgE myeloma, or
o. graft-versus-host reaction.

These species are distinct because of the pathological conditions differ in etiologies and therapeutic endpoints; thus each condition represents patentably distinct subject matter.

Applicant is required under 35 USC 121 (1) to elect a single disclosed species to which the claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

11. In addition to the species election set forth in Sections 9 and 10 above, this application contains claims directed to the following patentably distinct species of the claimed inventions wherein:

If Group III or IV is elected: Applicant is required to elect a particular combination therapy of IgE-mediated disorder type from the following (e.g. see Claims 40-50, p 62-65 Specification, Combination Therapies):

a. antihistamine,
b. bronchodialator,
c. glucocorticoid,
d. allergen desensitization, or
e. NSAID.

These species are distinct because of their physicochemical properties, specificity, utility and modes of action. Therefore, they are patentably distinct.

Applicant is required under 35 USC 121 (1) to elect a single disclosed species to which the claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

12. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

13. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

14. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. *Process claims that depend from or otherwise include all the limitations of the patentable product* will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. *Failure to do so may result in a loss of the right to rejoinder.*

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yunsoo Kim whose telephone number is 571-272-3176. The examiner can normally be reached on Monday thru Friday 8:30 - 5:00PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Yunsoo Kim
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Technology Center 1600
November 29, 2004

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